This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

RHÔNE-POULENC

Rhône-Poulenc Ag Company

7 December 1999

U.S. Environmental Protection Agency
Office of Pesticide Programs
Document Processing Desk
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Ms. Deanna Scher
Reregistration and Special Review Division

RE: PHOSALONE TOLERANCE MAINTENANCE

Dear Ms. Scher:

This is our 30 day response to OPP's preliminary human health risk assessment for phosalone, regarding errors, confidential business information (CBI) and planned data.

RPAC does not consider that any information in the OPP assessment to be CBI. We will inform RP country organizations of the requests for label revisions to specifically limit the number of applications of phosalone and will request that each organization discuss this with their national authority.

Product Chemistry Data Requirements:

- OPPTS 830.1600. RPAC will provide information on the source of starting materials within the next few days.
- OPPTS 830.1670. RPAC will provide a discussion on the formation of post-production impurities within the next few days.
- OPPTS 830.7050. RPAC will provide a study within the next few days to fulfill the requirement for UV spectra. This was not previously submitted because it was not required by the 1987 registration standard for phosalone and is shown as "not applicable" in the 1997 draft guidance for import tolerances.

Toxicology Data Requirements:

- EPA 84-2. RPAC will conduct a study for unscheduled DNA synthesis (UDS) to confirm questionable results in the submitted study. The timeframe for completing this study has not yet been confirmed but that information will be relayed as soon as possible.

In the Toxicology Chapter for the Reregistration Eligibility Document (9/15/99; D256366), a request was made for additional data or an explanation to upgrade the rat metabolism study under EPA 85-1. RPAC is unable to provide the requested additional data on metabolite

PO Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709-2014
(919) 549-2000

identification in urine due to the unavailability of samples for further analysis. However, a full new study is planned for initiation in approximately April 2000, with completion about June 2001. The new study will be provided to US-EPA upon completion. We note the Agency's conclusion that the lack of such data is not expected to affect risk calculations and that the existing study provides reasonable understanding of absorption, distribution, elimination, and blood and plasm concentrations.

We believe that there is a technical error in comments made in the Preliminary Human Health Risk Assessment (11/1/99; DP Barcode D256055) and in Toxicology Chapter (9/15/99; DP Barcode D256366) regarding the need for a developmental neurotoxicity study for phosalone (as confirmatory data only). The Report of the HIARC (8/12/99; PC Code 097701) concluded that a developmental neurotoxicity study is not needed for phosalone. This was affirmed by the FQPA Safety Factor Committee report (9/13/99; PC Code 097701). The Toxicology Chapter comments only that a data call-in for such studies for a broad category of pesticides has been issued; it also comments that such information would not be expected to change calculated risk. Although no data call-in (DCI) has been received for a developmental neurotoxicity study on phosalone, we've received the September 10, 1999 DCI on other products. On the Note To Reader page of this DCI, it states under the second overview of modifications entitled "List of Active Ingredients Subject to this Notice" that "The names of 3 organophosphates, cadusafos, mevinphos, and phosalone, have been removed from the list of active ingredients subject to this Data Call-In Notice...." Thus, we believe that comments regarding the need for this study are in error. We would like to request a waiver for a requirement for a developmental neurotoxicity study, based on all of the above stated comments.

Residue Chemistry Requirements

RPAC has several field trials underway in Canada and will provide them to the Agency upon completion later this year. RPAC feels that the additional data requirements beyond the currently available and soon to be completed field trial data are unnecessary, given market share and potential treated imported commodities, and will request a meeting with the Agency to discuss this further prior to making a response.

In the November 1, 1999 document entitled "Anticipated Residue Estimates for Purposes of Dietary Exposure Refinement for Select Import Commodities" there is an error on page 6. On this page, footnote 2 is referred to as footnote 1 at the bottom of the page. The reference within the text is correctly noted as footnote 2.

Please contact me at 919/549-2787 if you have any questions on this submission.

Sincerely,

Lizbeth A. Rea

Lizbeth A. Rea
Registration Manager